

### **REMARKS**

#### **Status of the Claims and Amendment**

Claims 1-47, 50-53, and 56-60 are all the claims pending in this application. Claim 60 is allowed. Claims 1-59 are rejected. Applicants' election with traverse of Group I (claims 1-60) on July 29, 2009, is acknowledged. Claims 1-59 insofar as being directed to a heterocyclic or heteroaromatic compound of formula I are withdrawn as being drawn to a non-elected invention.

Claims 1-9, 22-47, 50-53, 56, and 57 have been amended to delete heterocyclic and heteroaromatic compounds of formula I in response to objections to the claims.

Claims 1-9, 22-47, 50-53, and 57 have been amended to delete "derivative", and claim 59 has been amended correct the misspelling of "drag" to "drug".

Claims 1-47, 50-53, and 56-58 have been amended to delete "hydrate".

Claims 1-47, 50-53, and 56-57 have been amended to correct a typographical error, i.e., remove parentheses.

Claims 48, 49, 54 and 55 have been canceled without prejudice.

No new matter is added.

#### **Claim of Priority**

Applicants thank the Examiner for acknowledging Applicants' claim to priority and receipt of certified copies of the priority documents on the PTO Form PTOL-326. However, Applicants note that page 2 of the Office Action erroneously cites the International Application as PCT/JP2002/12409 and the foreign priority Applications as JP 2001-363336 and JP 2002-248888.

The present Application is a 371 National Stage of PCT/JP2004/009398 and claims priority from JP 2003-181930 filed June 26, 2003, JP 2003-373511 filed October 31, 2003, and JP 2004-128663 filed April 23, 2004. Applicants respectfully request the Examiner indicate acknowledgement of the claim to priority of JP 2003-181930 filed June 26, 2003, JP 2003-373511 filed October 31, 2003, and JP 2004-128663 filed April 23, 2004, as well as receipt of copies of the priority documents in the next Office Communication.

#### **Information Disclosure Statements**

Applicants thank the Examiner for consideration of the Information Disclosure Statements filed December 23, 2005, July 19, 2007, September 18, 2008, and February 25, 2009, by returning signed and initialed copies of the PTO Forms SB/08 submitted therewith.

#### **Response to Claim Objections**

Claims 1-59 are objected to because the claims contain phrases referencing heterocyclic or heteroaromatic compounds of formula I which belong to non-elected Group II. Removal of the phrases is suggested.

In response, and solely to advance prosecution of the present application, claims 1-9, 22-47, 50-53, 56, and 57 have been amended remove heterocyclic and heteroaromatic compounds of formula I. Claims 48, 49, 54 and 55 have been canceled without prejudice.

Withdrawal of the grounds of objection is respectfully requested.

#### **Response to Claim Rejections Under 35 U.S.C. § 112**

##### **1. Indefiniteness Rejection**

Claims 1-59 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claims 1-58 is asserted to be vague and indefinite because of the term “derivative”.

Claim 59 is asserted to be vague and indefinite because the term “drag” appears to be a misspelling.

In response, and solely to advance prosecution of the present application, claims 1-9, 22-47, 50-53, and 57 have been amended to delete “derivative”, and claim 59 has been amended correct the misspelling of “drag” to “drug”.

Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

## **2. Enablement Rejection**

Claims 1-59 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and hydrates of the claimed compounds.

The Office Action appears to assert that the specification does not enable the presently claimed compounds because of the absence of any working example of a solvate (such as a hydrate), the lack of predictability in the art, and the broad scope of the claims. The Office Action appears to base this rejection upon the recitation of “solvates” in the claims because it is asserted that the claims are drawn to solvates, yet the examples do not produce a solvate.

Initially, Applicants note that to comply with the enablement requirement, a working example is not required. M.P.E.P. § 2164.02 (stating that “[t]he specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.” A lack of working examples should never be the sole reason for rejecting the claimed invention. *Id.* Further, “[t]he scope of enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required.” M.P.E.P. § 2164.03.

The presently claimed compounds may be prepared according to organic synthesis methods known in the art. Further, it is common technical knowledge that compounds are often synthesized as hydrates so as to increase their solubility in aqueous solvents. Thus, one of skill in the art would fully understand, from the guidance presented in the specification regarding synthesis the claimed compound, how to generate a hydrate of the claimed compound. For instance, as disclosed at page 18, 2<sup>nd</sup> to last full paragraph to page 49 and Examples, the claimed compounds may be synthesized according to conventional organic synthesis methods known and commonly practiced in the art. Also, as disclosed at page 17, of the specification, the claimed compound may become a hydrate by being exposed to the atmosphere or by recrystallization. Accordingly, it would be a matter of routine experimentation for one of skill in the art would be enabled to make the claimed hydrate compounds from both the guidance set forth in the specification, and the knowledge possessed by one of ordinary skill in the art.

Nevertheless, and solely to advance prosecution of the present application, claims 1-47, 50-53, and 56-58 have been amended to delete “hydrate”.

Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

#### **Response to Claim Rejections Under 35 U.S.C. § 102**

Claims 1-59 are rejected under 35 U.S.C. § 102(b) as being anticipated by Adam *et al.* (U.S. Patent No. 6,107,342).

The Office Action appears to assert that Adam discloses the claimed compound at column 13, lines 30-53 and column 28, lines 17-61.

Applicants respectfully disagree and assert that the presently claimed compounds are not explicitly or inherently anticipated by the compounds disclosed in Adam at column 13, lines 30-

53 or column 28, lines 17-61 because at least the R<sup>1</sup> and R<sup>2</sup> groups disclosed do not correspond to the claimed compounds.

Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

### **Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Tu A. Phan/

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

---

Tu A. Phan, Ph.D.  
Registration No. 59,392

Date: December 3, 2009